

DATE OUT: 12/JAN/10

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [X]

BARCODE NO.: D371159

REG./FILE SYMBOL NO.: 8622-68

PRODUCT NAME: CALIRUS 150

MRID NOS.: 460409-01, -02, and 462682-01

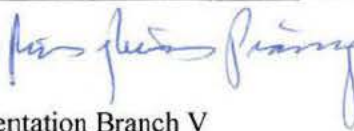
COMPANY NAME: Ameribrom, Inc.

ACTION CODE: 676

CONTRACTOR: CSC

PROJECT CODE: PRD-20 OPII

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### INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case numbers 0636, 0649, 4025, and 4026, was completed in July 2006 (amended May 2009) for the Technical Grade Active Ingredient (TGAI) Copper, which pertains to the Copper Sulfates, the Copper Compounds, Copper Oxides, and Copper Salts, respectively. According to the RED, the generic data base supporting the reregistration of agricultural uses of copper has been reviewed and found to be substantially complete.

In the 8-month response to the Copper RED, Ameribrom, Inc. provided a Confidential Statement of Formula (CSF) for the basic formulation, dated 4/18/05; and a draft label. The registrant cited product chemistry data, including MRID Nos. 460409-01, -02, and 462682-01. The registrant is requesting reregistration of their product, CALIRUS 150, EPA Reg. No. 8622-68.

### FINDINGS:

1. EPA Reg. No. 8622-68 is an end-use fungicide containing the active ingredients mono- and dipotassium salts of phosphorous acid and copper sulfate, with label claim nominal concentrations of 10.30% and 0.15%, respectively. The product is a fungicide for use in controlling *Pythium*, *Plasmodiophora*, Downy Mildews, *Alternaria* and *Phytophthora* on agronomic crops. The current formulation of the product is produced by an integrated system.
2. The CSF for the basic formulation is acceptable with comments: (a) under box 7, the density of the product should be 9.25 lbs/gal (which corresponds to the reported relative density of 1.11); and (b) under box 13b for the [REDACTED] should be deleted.

The nominal concentrations of the active ingredients agree with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredients and inert ingredient(s) are acceptable in accordance with 40 CFR §158.175(b)(2). All inert formulation components are cleared for use in pesticide formulations.

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3. The data cited in MRID Nos. 460409-01, -02, and 462682-01 satisfy the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method.

Except for Finding 4, the data also satisfy the product chemistry requirements as specified in 40 CFR §158.190 (the new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product. [Note that waivers were requested, and have been approved, for requirements concerning Guideline 830.6315 (Flammability/Flame Extension) and 830.6316 (Explosibility).]

4. The referenced studies on Storage Stability and Corrosion Characteristics are not acceptable because the levels of the copper sulfate active ingredient were not analyzed; only the phosphite concentrations were determined at levels ~ 5.77%. Furthermore, the container used in the study was not the container of choice (LDPE vs. HDPE). Therefore, the requirements concerning Guidelines 830.6317 (Storage Stability) and 830.6319 (Corrosion Characteristics) are not satisfied.
5. The Enforcement Analytical Method for the determination of copper content in the product is presented in MRID No. 460409-01. The method is adequate and satisfies the requirements under Guideline 830.1800.
- 6a. The Ingredients Statement on the draft label must be revised as follows:
- The active ingredient name Copper Sulfate must be changed to Copper Sulfate Pentahydrate.
  - The CAS number, 7758-99-8, must be added after the name Copper Sulfate Pentahydrate.
  - The metallic copper equivalent of Copper Sulfate Pentahydrate, 0.0381%, must be added under the Ingredients statements.
- 6b. Data are present to trigger the need for a Physical or Chemical Hazards Statement. The following revisions must be made to the label: (1) Add the heading "Physical or Chemical Hazards" to the product label immediately below the Environmental Hazards statement; and (2) under the new Physical or Chemical Hazards Statement, place a statement regarding the incompatibility of the product with other chemicals (e.g., strong oxidants) as evidenced by the data provided in response to Guideline 830.6314 (Oxidation/ Reduction; Chemical Incompatibility).
- 6c. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10 (i)(2)(ix) and PR Notice 83-3. The following revision to the label is recommended: Under the Pesticide Disposal section, change "disposal or excess pesticide" to read "disposal of excess pesticide;"

NOTE TO CRM: The labeling issues should be addressed during label review.

## **CONCLUSIONS:**

After submission of data as noted in Finding 4, the registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. **8622-68**.



**Product Chemistry Data****Subgroup A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)****Product Identity, Composition, and Analysis**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>40 CFR §</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.1550 Product Identity and Composition	158.320	460409-01 and CSF	Y
.1600 Description of Materials Used to Produce the Product	158.325	460409-01	Y
.1620 Description of Production Process	158.330	460409-01	Y
.1650 Description of Formulation Process	158.335	<i>[Not required for products produced by an integrated system]</i>	N/A
.1670 Discussion of Formation of Impurities	158.340	460409-01	Y
.1700 Preliminary Analysis	158.345	460409-01  Note: Results from method validation (i.e., precision, accuracy) were reported for this non-GLP study.	Y
.1750 Certified Limits	158.350	460409-01 and CSF	Y
.1800 Enforcement Analytical Method	158.355	460409-01	Y

**Subgroup B: Series 830.6302 - 7950 (40 CFR §158.310)**

Physical and Chemical Properties

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
Note: Data reported in MRID Nos. 460409-02 and 462682-01 were developed by testing a product referred to as AG3-Liquid. A comparison of information provided in MRID No. 460409-01 and the CSF for CALIRUS 150 confirm that AG3-Liquid is the same as the product, CALIRUS 150.			
.6302 Color	Aqua blue; 10BG 8/4 according to the Munsell Colour System; at 20.0±0.5°C	460409-02	Y
.6303 Physical State	Liquid at 20.0±0.5°C	460409-02	Y
.6304 Odor	Odorless at 20.0±0.5°C	460409-02	Y
.6314 Oxidation/ Reduction: Chemical Incompatibility	Compatible with water, 10% monoammonium phosphate solution, zinc granules, and kerosene. Incompatible with 10% potassium permanganate solution.	460409-02	Y
.6315 Flammability/Flame Extension	The product is approximately [REDACTED] by weight and, therefore, could not be considered flammable.	460409-02	W
.6316 Explodability	The product is approximately [REDACTED] by weight and, therefore, could not be considered explosive.	460409-02	W
.6317 Storage Stability	The copper sulfate active ingredient levels were not analyzed.  Container used was not the container of choice.	462682-01	U

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6319 Miscibility	The product is not intended for dilution with petroleum solvents.	460409-02	Y
.6320 Corrosion Characteristics	The copper sulfate active ingredient levels were not analyzed.  Container used was not the container of choice.	462682-01	U
.6321 Dielectric Breakdown Voltage	The product is not intended for use around electrical equipment.	460409-02	Y
.7000 pH	6.56 (1% aqueous dispersion) at 25°C	460409-02	Y
.7100 Viscosity	1.36 mm <sup>2</sup> /s at 20.0±0.5°C; 0.884 mm <sup>2</sup> /s at 40.0±0.5°C	460409-02	Y
.7300 Density/Relative Density	1.11 at 20.0±0.5°C (relative density)	460409-02	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required

Enforcement Analytical Method, Guideline 830.1800 (MRID No. 460409-01)

A Flame Atomic Absorption Spectrometry method is used to determine copper content in the product. Samples are diluted to bring the copper concentration into the optimum range. Four calibration standards are prepared. The test materials are then analyzed by AA spectroscopy under the following conditions:

Method:	AA
Instrument:	Spectra AA 220 plus, Varian and associated equipment
Wavelength:	324.7 nm
Flame type:	air/acetylene

This method is found to be adequate and would satisfy Guideline 830.1800.

